

2007 DRAFTING REQUEST

Bill

Received: **02/05/2007**

Received By: **rryan**

Wanted: **As time permits**

Identical to LRB:

For: **Fred Risser (608) 266-1627**

By/Representing: **Terry Tuschen**

This file may be shown to any legislator: **NO**

Drafter: **rryan**

May Contact:

Addl. Drafters: **agary**

Subject: **Health - miscellaneous**

Extra Copies: **Rep. Wieckert
DAK**

Submit via email: **YES**

Requester's email: **Sen.Risser@legis.wisconsin.gov**

Carbon copy (CC:) to: **rep.wieckert@legis.wisconsin.gov**

Pre Topic:

No specific pre topic given

Topic:

Anatomical gfits

Instructions:

See Attached

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/P2	rryan 08/15/2007	csicilia 08/17/2007	nnatzke 07/12/2007	_____	cdurert 07/12/2007		State Crime
/1	rryan	csicilia	rschluet	_____	sbasford		State

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/2			jfrantze	_____	lparisi	cduerst	
			10/03/2007	_____	10/03/2007	10/08/2007	

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"1/2" @ intro. 11-2-2007

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Handwritten signatures and dates:
10/30/07, 10/3/07

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08/17/2007 _____

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6/17/07

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FE Sent For:

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LRB

Research (608-266-0341)

Library (608-266-7040)

Legal (608-266-3561)

LRB

3/14/07

Mtg. with Risser & Wieckert Staff
 UW Hosp. & Clinics & UW OPO
 Reps. of Tissue Banks, Froedert

Maintain current law on coroners/MG
 tissue banks, for credit,
 mandatory request

want everyone who can consent to
 gift under § 9 also to be
 able to authorize gift before
 death

make sure can donate to a
 specific OPO

Keep existing penalty on sale of
 organs - Keep it in 146, don't
 move to 157.06 because covers
 sale from live persons, not just death
 update def. of "part"

Make age at which may donate
 15 $\frac{1}{2}$
 Leave emancipated minor undefined

Registry - allow DHS to create
 a registry - if does,
 must promulgate rules

DOT must cooperate

what does "examination" under § 14 cover?

chart, history, phys. exam, discussion w/ family
don't need auth for the physical exam, but as a result of HIPAA need auth. to review records.

Is ok w/ group if I change "document of gift" to "record of gift" to avoid calling inclusion in a registry a "document."

Bob
miller
(UW Hosp & Clinics)
3/14/07

Draft 03-14-07

QUESTIONS CONCERNING 2006 UNIFORM ANATOMICAL GIFT ACT

SUBJECT	COMMENT	SECTION OF 2006 UAGA	EXISTING WISCONSIN LAW
SCOPE OF PERSONS WHO CAN SIGN DONATION PRIOR TO DEATH	This list should include all the persons listed in section 9.	4	157.06(3)
PERMITTED PURPOSES OF DONATIONS	Donation of organs to a specific OPO for transplantation should be permitted as in existing law.	11(a)	157.06(6)(a)(1)
MANDATORY REQUEST	Not in UAGA 2006; should it be retained	15 (relies on federal law)	157.06(5)
CRIMINAL PENALTIES FOR SALE OF ORGANS	Existing Wisconsin law is broader; keep existing law	16	146.345
VALIDITY OF DIRECTIVES UNDER PRIOR LAW	Not addressed in UAGA 2006	could be added to 19	157.06(11) (needs to be broadened to)
USE OF TERM "EXECUTE"	Circular definition of signing and executing creates ambiguity; in section 19 replace "executed" with "made"	19 needs clarification	No comparable problem
CORONERS/ MEDICAL EXAMINERS	Existing Wisconsin law is more favorable to transplantation; keep existing law	23 22b	157.06(4), (4m), and (4r)
CONSENT LANGUAGE/ FORM REQUIREMENTS	Existing Wisconsin law requires certain disclosures to be made (e.g. commer- cial use of tissue); Keep existing law	No comparable sections	157.06(6m) and (9m)

assume just
want 5(b) 1.?

15 OK

REVISED UNIFORM ANATOMICAL GIFT ACT (2006)

drafted by the

**NATIONAL CONFERENCE OF COMMISSIONERS
ON UNIFORM STATE LAWS**

and by it

**APPROVED AND RECOMMENDED FOR ENACTMENT
IN ALL THE STATES**

at its

**ANNUAL CONFERENCE
MEETING IN ITS ONE-HUNDRED-AND-FIFTEENTH YEAR
HILTON HEAD, SOUTH CAROLINA**

July 7-14, 2006

WITH PREFATORY NOTE AND COMMENTS

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By

**NATIONAL CONFERENCE OF COMMISSIONERS
ON UNIFORM STATE LAWS**

October 13, 2006

ABOUT NCCUSL

The **National Conference of Commissioners on Uniform State Laws (NCCUSL)**, now in its 115th year, provides states with non-partisan, well-conceived and well-drafted legislation that brings clarity and stability to critical areas of state statutory law.

Conference members must be lawyers, qualified to practice law. They are practicing lawyers, judges, legislators and legislative staff and law professors, who have been appointed by state governments as well as the District of Columbia, Puerto Rico and the U.S. Virgin Islands to research, draft and promote enactment of uniform state laws in areas of state law where uniformity is desirable and practical.

- NCCUSL strengthens the federal system by providing rules and procedures that are consistent from state to state but that also reflect the diverse experience of the states.
- NCCUSL statutes are representative of state experience, because the organization is made up of representatives from each state, appointed by state government.
- NCCUSL keeps state law up-to-date by addressing important and timely legal issues.
- NCCUSL's efforts reduce the need for individuals and businesses to deal with different laws as they move and do business in different states.
- NCCUSL's work facilitates economic development and provides a legal platform for foreign entities to deal with U.S. citizens and businesses.
- NCCUSL Commissioners donate thousands of hours of their time and legal and drafting expertise every year as a public service, and receive no salary or compensation for their work.
- NCCUSL's deliberative and uniquely open drafting process draws on the expertise of commissioners, but also utilizes input from legal experts, and advisors and observers representing the views of other legal organizations or interests that will be subject to the proposed laws.

NCCUSL is a state-supported organization that represents true value for the states, providing services that most states could not otherwise afford or duplicate.

DRAFTING COMMITTEE ON REVISED UNIFORM ANATOMICAL GIFT ACT (2006)

The Committee appointed by and representing the National Conference of Commissioners on Uniform State Laws in revising this Act consists of the following individuals:

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Copies of the Act may be obtained from:

NATIONAL CONFERENCE OF COMMISSIONERS ON UNIFORM STATE LAWS
211 E. Ontario Street, Suite 1300
Chicago, IL 60611
312-915-0195
www.nccusl.org

REVISED UNIFORM ANATOMICAL GIFT ACT

TABLE OF CONTENTS

SECTION 1. SHORT TITLE	10
SECTION 2. DEFINITIONS.....	10
SECTION 3. APPLICABILITY	17
SECTION 4. WHO MAY MAKE ANATOMICAL GIFT BEFORE DONOR'S DEATH.....	17
SECTION 5. MANNER OF MAKING ANATOMICAL GIFT BEFORE DONOR'S DEATH.....	19
SECTION 6. AMENDING OR REVOKING ANATOMICAL GIFT BEFORE DONOR'S DEATH.....	23
SECTION 7. REFUSAL TO MAKE ANATOMICAL GIFT; EFFECT OF REFUSAL.....	26
SECTION 8. PRECLUSIVE EFFECT OF ANATOMICAL GIFT, AMENDMENT, OR REVOCATION.....	28
SECTION 9. WHO MAY MAKE ANATOMICAL GIFT OF DECEDENT'S BODY OR PART.....	32
SECTION 10. MANNER OF MAKING, AMENDING, OR REVOKING ANATOMICAL GIFT OF DECEDENT'S BODY OR PART.....	36
SECTION 11. PERSONS THAT MAY RECEIVE ANATOMICAL GIFT; PURPOSE OF ANATOMICAL GIFT.....	38
SECTION 12. SEARCH AND NOTIFICATION.....	43
SECTION 13. DELIVERY OF DOCUMENT OF GIFT NOT REQUIRED; RIGHT TO EXAMINE.....	44
SECTION 14. RIGHTS AND DUTIES OF PROCUREMENT ORGANIZATION AND OTHERS.....	44
SECTION 15. COORDINATION OF PROCUREMENT AND USE.....	47
SECTION 16. SALE OR PURCHASE OF PARTS PROHIBITED.....	48
SECTION 17. OTHER PROHIBITED ACTS	48
SECTION 18. IMMUNITY.....	49
SECTION 19. LAW GOVERNING VALIDITY; CHOICE OF LAW AS TO EXECUTION OF DOCUMENT OF GIFT; PRESUMPTION OF VALIDITY.....	50
SECTION 20. DONOR REGISTRY.....	51
SECTION 21. EFFECT OF ANATOMICAL GIFT ON ADVANCE HEALTH-CARE DIRECTIVE	53
SECTION 22. COOPERATION BETWEEN [CORONER] [MEDICAL EXAMINER] AND PROCUREMENT ORGANIZATION.....	54
SECTION 23. FACILITATION OF ANATOMICAL GIFT FROM DECEDENT WHOSE BODY IS UNDER JURISDICTION OF [CORONER] [MEDICAL EXAMINER].....	55
SECTION 24. UNIFORMITY OF APPLICATION AND CONSTRUCTION.....	58
SECTION 25. RELATION TO ELECTRONIC SIGNATURES IN GLOBAL AND NATIONAL COMMERCE ACT.....	58
SECTION 26. REPEALS	59
SECTION 27. EFFECTIVE DATE.....	59

REVISED UNIFORM ANATOMICAL GIFT ACT

Prefatory Note

As of January, 2006 there were over 92,000 individuals on the waiting list for organ transplantation, and the list keeps growing. It is estimated that approximately 5,000 individuals join the waiting list each year. *See* "Organ Donation: Opportunities for Action," Institute of Medicine of the National Academies (2006) www.nap.edu. Every hour another person in the United States dies because of the lack of an organ to provide a life saving organ transplant.

The lack of organs results from the lack of organ donors. For example, according to the Scientific Registry of Transplant Recipients in 2005 when there were about 90,000 people on the organ transplant waiting list, there were 13,091 individuals who died under the age of 70 using cardiac and brain death criteria and who were eligible to be organ donors. Of these, only 58% or 7,593 were actual donors who provided just over 23,000 organs. Living donors, primarily of kidneys, contributed about 6,800 more organs. Between them about 28,000 organs were transplanted into patients on the waiting list in 2005. (*See* www.optn.org).

The 2005 data on cadaveric organ donors suggests there were 5,498 individuals who died that year that could have been donors who weren't and that had they been organ donors there would have been approximately 17,000 additional organs potentially available for transplantation. (*See generally*, www.unos.org and www.ustransplant.org). However, these numbers to some extent are only estimates. First, they exclude individuals dying over the age of 70. Second, the data are self reported for eligible donors. Indicative of the absence of precision in this area is the report from the Institute of Medicine. According to the IOM, it has been estimated that donor-eligible deaths range between 10,500 and 16,800 per year. *See* "Organ Donation: Opportunities for Action," Institute of Medicine of the National Academies (2006) at page 27. www.nap.edu Using the 2005 figures for deceased organ donors, this would suggest that between approximately 3,000 and 9,000 decedents could have been donors but weren't. Further, if one assumes an average of three solid organs recovered from each of them, there could be between 9,000 and 27,000 more organs that might have been available to transplant into individuals on the waiting list.

The data for eye and tissue is, however, more encouraging. On an annual basis there are approximately 50,000 eye donors and tissue donors and over 1,000,000 ocular and tissue transplants.

This Revised Uniform Anatomical Gift Act ("UAGA") is promulgated by the National Conference of Commissioners on Uniform State Laws ("NCCUSL") to address in part the critical organ shortage by providing additional ways for making organ, eye, and tissue donations. The original UAGA was promulgated by NCCUSL in 1968 and promptly enacted by all states. In 1987, the UAGA was revised and updated, but only 26 states adopted that version. Since 1987, many states have adopted non-uniform amendments to their anatomical gift acts. The law among the various states is no longer uniform and harmonious, and the diversity of law is an impediment to transplantation. Furthermore the federal government has been increasingly active in the organ transplant process.

Since 1987, there also have been substantial improvements in the technology and practice of organ, eye, and tissue transplantation and therapy. And, the need for organs, eyes, and tissue for research and education has increased to assure more successful transplantations and therapies. The improvements in technology and the growing needs of the research community have correspondingly increased the need for more donors.

This 2006 Revised UAGA is promulgated with the substantial and active participation of the major stakeholders representing donors, recipients, doctors, procurement organizations, regulators, and others affected. The Drafting Committee held four meetings with the stakeholders beginning on Friday morning and ending Sunday noon, reading and discussing each section of the drafts word by word (Chicago, December 3-5, 2004; Philadelphia, March 18-20, 2005; Chicago, November 2-4, 2005; and Detroit, April 21-23, 2006). The following stakeholders were actively engaged in the dialogue working for a consensus that could and should be adopted on a uniform basis to facilitate the anatomical gifts of human bodies and parts: American Bar Association, American Medical Association, American Lung Association, Association of Organ Procurement Organizations, American Association of Tissue Banks, Eye Bank Association of America, Health Law Institute and Center for Race and Bioethics, Life Alaska Donor Services, Musculoskeletal Transplant Foundation, National Association of Medical Examiners, National Disease Research Interchange, National Kidney Foundation, North American Transplant Coordinators Organization, RTI Donor Services, United Network for Organ Sharing (UNOS) and United States Department of Health & Human Services. In addition, there were many who contributed their views and comments by correspondence, including the Funeral Consumers Alliance, Inc. and Funeral Ethics Organization.

This [act] adheres to the significant policy determinations reflected in existing anatomical gift acts. First, the [act] is designed to encourage the making of anatomical gifts. Second, the [act] is designed to honor and respect the autonomy interest of individuals to make or not to make an anatomical gift of their body or parts. Third, the [act] preserves the current anatomical gift system founded upon altruism by requiring a positive affirmation of an intent to make a gift and prohibiting the sale and purchase of organs. This [act] includes a number of provisions, discussed below, that enhance these policies.

History of 1968 and 1987 Acts

The first reported medical transplant occurred in the third century. However, medical miracles flowing from transplants are truly a modern story beginning in the first decade of the twentieth century with the first successful transplant of a cornea. But, not until three events occurred in the twentieth century, in addition to the development of surgical techniques to effectuate a transplant, could transplants become a viable option to save and meaningfully extend lives.

The first event was the development in the late 1960s of the first set of neurological criteria for determining death. These criteria allowed persons to be declared dead upon the cessation of all brain activity. Ultimately these criteria, together with the historic measure of determining death by cessation of circulation and respiration, were incorporated into Section 1 of

the Uniform Determination of Death Act providing that: "An individual who has sustained either (1) irreversible cessation of circulatory and respiratory function, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead."

The second event, following shortly after Dr. Christian Barnard's successful transplant of a heart in November, 1967, was this Conference's adoption of the first Uniform Anatomical Gift Act. In short order, every jurisdiction uniformly adopted the 1968 Act. The most significant contribution of the 1968 Act was to create a right to donate organs, eyes, and tissue. This right was not clearly recognized at common law. By creating this right, individuals became empowered to donate their parts or their loved one's parts to save or improve the lives of others.

The last event was the development of immunosuppressive drugs that prevented organ recipients from rejecting transplanted organs. This permitted many more successful organ transplants, thus contributing to the rapid growth in the demand for organs and the need for changes in the law to facilitate the making of anatomical gifts.

In 1987, a revised Uniform Anatomical Gift Act was promulgated to address changes in circumstances and in practice. Only 26 jurisdictions enacted the 1987 revision. Consequently, there is significant non-uniformity between states with the 1968 Act and those with the 1987 revisions. Neither of those acts comports with changes in federal law adopted subsequent to the 1987 Act relating to the role of hospitals and procurement organization in securing organs, eyes, and tissues for transplantation. And, both of them have impediments that are inconsistent with a policy to encourage donation.

The two previous anatomical gift acts, as well as this [act], adhere to an "opt in" principle as its default rule. Thus, an individual becomes a donor only if the donor or someone acting on the donor's behalf affirmatively makes an anatomical gift. The system universally adopted in this country is contrary to the system adopted in some countries, primarily in Europe, where an individual is deemed to be a donor unless the individual or another person acting on the individual's behalf "opts out." This other system is known as "presumed consent." While there are proponents of presumed consent who believe the concept of presumed consent could receive in the future a favorable reception in this country, the professional consensus appears to be not to replace the present opt-in principle at this time. See "Organ Donation: Opportunities in Action," Institute of Medicine of the National Academies (2006) at page 12.

Scope of the 2006 Revised Act

This [act] is limited in scope to donations from deceased donors as a result of gifts made before or after their deaths. Although recently there has been a significant increase in so-called "living donations," where a living donor immediately donates an organ (typically a kidney or a section of a liver) to a recipient, donations by living donors are not covered in this [act] because they raise distinct and difficult legal issues that are more appropriate for a separate act.

A majority of donors or prospective donors are candidates for donation of eyes or tissue, but only a small percentage of individuals die under circumstances that permit an anatomical gift of an organ. To procure an anatomical gift for transplantation, therapy, research, or education, a

donor or prospective donor must be declared dead (*see* Uniform Determination of Death Act). In cases of potential organ donation, measures necessary to ensure the medical suitability of an organ for transplantation or therapy are administered to a patient who is dead or near death to determine if the patient could be a prospective donor.

Pursuant to federal law, when a donor or a patient who could be a prospective donor is dead or near death, a procurement organization, or a designee, must be notified. The organization begins to develop a medical and social history to determine whether the dying or deceased individual's body might be medically suitable for donation. If the body of a dying or deceased person might be medically suitable for donation, the procurement organization checks for evidence of a donation, if not otherwise known, and seeks consent to donation from authorized persons, if necessary. In the case of an organ, the organ procurement organization obtains from the Organ Procurement and Transplantation Network ("OPTN") a prioritized list of potential recipients from the national organ waiting list and takes the necessary steps to see that the organ finds its way to the appropriate recipient. If eye or tissue is donated, the appropriate procurement organization procures the eye or tissue and takes the necessary steps to screen, test, process, store, or distribute them as required for transplantation, therapy, research, or education. All must be done expeditiously.

Recent technological innovations have increased the types of organs that can be transplanted, the demand for organs, and the range of individuals who can donate or receive an organ, thereby increasing the number of organs available each year and the number of transplantations that occur each year. Nonetheless, the number of deaths for lack of available organs also has increased. While the Commissioners are under no illusion that any anatomical gift act can fully satisfy the need for organs, any change that could increase the supply of organs and thus save lives is an improvement.

Transplantation occurs across state boundaries and requires speed and efficiency if the organ is to be successfully transplanted into a recipient. There simply is no time for researching and conforming to variations of the laws among the states. Thus, uniformity of state law is highly desirable. Furthermore, the decision to be a donor is a highly personal decision of great generosity and deserves the highest respect from the law. Because current state anatomical gift laws are out of harmony with both federal procurement and allocation policies and do not fully respect the autonomy interests of donors, there is a need to harmonize state law with federal policy as well as to improve the manner in which anatomical gifts can be made and respected.

Summary of the Changes in the Revised Act

This revision retains the basic policy of the 1968 and 1987 anatomical gift acts by retaining and strengthening the "opt-in" system that honors the free choice of an individual to donate the individual's organ (a process known in the organ transplant community as "first person consent" or "donor designation"). This revision also preserves the right of other persons to make an anatomical gift of a decedent's organs if the decedent had not made a gift during life. And, it strengthens the right of an individual not to donate the individual's organs by signing a refusal that also bars others from making a gift of the individual's organs after the individual's death. This revision:

1. Honors the choice of an individual to be or not to be a donor and strengthens the language barring others from overriding a donor's decision to make an anatomical gift (Section 8);

2. Facilitates donations by expanding the list of those who may make an anatomical gift for another individual during that individual's lifetime to include health-care agents and, under certain circumstances, parents or guardians (Section 4);

3. Empowers a minor eligible under other law to apply for a driver's license to be a donor (Section 4);

4. Facilitates donations from a deceased individual who made no lifetime choice by adding to the list of persons who can make a gift of the deceased individual's body or parts the following persons: the person who was acting as the decedent's agent under a power of attorney for health care at the time of the decedent's death, the decedent's adult grandchildren, and an adult who exhibited special care and concern for the decedent (Section 9) and defines the meaning of "reasonably available" which is relevant to who can make an anatomical gift of a decedent's body or parts (Section 2(23));

5. Permits an anatomical gift by any member of a class where there is more than one person in the class so long as no objections by other class members are known and, if an objection is known, permits a majority of the members of the class who are reasonably available to make the gift without having to take account of a known objection by any class member who is not reasonably available (Section 9);

6. Creates numerous default rules for the interpretation of a document of gift that lacks specificity regarding either the persons to receive the gift or the purposes of the gift or both (Section 11);

7. Encourages and establishes standards for donor registries (Section 20);

8. Enables procurement organizations to gain access to documents of gifts in donor registries, medical records, and the records of a state motor vehicle department (Sections 14 and 20);

9. Resolves the tension between a health-care directive requesting the withholding or withdrawal of life support systems and anatomical gifts by permitting measures necessary to ensure the medical suitability of organs for intended transplantation or therapy to be administered (Sections 14 and 21);

10. Clarifies and expands the rules relating to cooperation and coordination between procurement organizations and coroners or medical examiners (Sections 22 and 23);

11. Recognizes anatomical gifts made under the laws of other jurisdictions (Section 19);
and

12. Updates the [act] to allow for electronic records and signatures (Section 25).

In addition, Section 2 provides a number of new definitions that are used in the substantive provisions of the [act] to clarify and expand the opportunities for anatomical gifts. These include: adult, agent, custodian, disinterested witness, donee, donor registry, driver's license, eye bank, guardian, know, license, minor, organ procurement organization, parent, prospective donor, reasonably available, recipient, record, sign, tissue, tissue bank, and transplant hospital.

Section 4 authorizes individuals to make anatomical gifts of their bodies or parts. It also permits certain persons, other than donors, to make an anatomical gift on behalf of a donor during the donor's lifetime. The expanded list includes agents acting under a health-care power of attorney or other record, parents of unemancipated minors, and guardians. The section also recognizes that it is appropriate that minors who can apply for a driver's license be empowered to make anatomical gifts, but, under Section 8(g), either parent can revoke the gift if the minor dies under the age of 18.

Section 5 recognizes that, since the adoption of the previous versions of this [act], some states and many private organizations have created donor registries for the purpose of making anatomical gifts. Thus, in addition to evidencing a gift on a donor card or driver's license, this [act] allows for the making of anatomical gifts on donor registries. It also permits gifts to be made on state-issued identification cards and, under limited circumstances, to be made orally. Except for oral gifts, there is no witnessing requirement to make an anatomical gift.

Section 6 permits anatomical gifts to be amended or revoked by the execution of a later-executed record or by inconsistent documents of gifts. It also permits revocation by destruction of a document of gift and, under limited circumstances, permits oral revocations.

Section 7 permits an individual to sign a refusal that bars all other persons from making an anatomical gift of the individual's body or parts. A refusal generally can be made by a signed record, a will, or, under limited circumstances, orally. By permitting refusals, this [act] recognizes the autonomy interest of an individual either to be or not to be a donor. The section also recognizes that a refusal can be revoked.

Section 8 substantially strengthens the respect due a decision to make an anatomical gift. While the 1987 Act provided that a donor's anatomical gift was irrevocable (except by the donor), until quite recently it had been a common practice for procurement organizations to seek affirmation of the gift from the donor's family. This could result in unnecessary delays in the recovery of organs as well as a reversal of a donor's donation decision. Section 8 intentionally disempowers families from making or revoking anatomical gifts in contravention of a donor's wishes. Thus, under the strengthened language of this [act], if a donor had made an anatomical gift, there is no reason to seek consent from the donor's family as they have no right to give it legally. *See* Section 8(a). Of course, that would not bar, nor should it bar, a procurement organization from advising the donor's family of the donor's express wishes, but that conversation should focus more on what procedures will be followed to carry out the donor's

wishes and on answering a family's questions about the process rather than on seeking approval of the donation. A limited exception applies if the donor is a minor at the time of death. In this case, either parent may amend or revoke the donor's anatomical gift. *See* Section 8(g).

Section 8 also recognizes that some decisions of a donor are inherently ambiguous, making it appropriate to adopt rules that favor the making of anatomical gifts. For example, a donor's revocation of a gift of a part is not to be construed as a refusal for others to make gifts of other parts. Likewise, a donor's gift of one part is not to be construed as a refusal that would bar others from making gifts of other parts absent an express, contrary intent.

Section 9 sets forth a prioritized list of classes of persons who can make an anatomical gift of a decedent's body or part if the decedent was neither a donor nor had signed a refusal. The list is more expansive than under previous versions of this [act]. It includes persons acting as agents at the decedent's death, adult grandchildren, and close friends.

Section 10 deals with the manner of making, amending, or revoking an anatomical gift following the decedent's death.

Section 11 deals with the passing of parts to named persons and more generally to eye banks, tissue banks, and organ procurement organizations. In part, the section is designed to harmonize this [act] with federal law, particularly with respect to organs donated for transplantation or therapy. The National Organ Transplant Act created the Organ Procurement and Transplantation Network ("OPTN") to facilitate the nationwide, equitable distribution of organs. Currently, United Network Organ Sharing ("UNOS") operates the OPTN under contract with the U.S. Department of Health and Human Services. When an organ donor dies, the donor's organs, barring the rare instance of a donation to a named individual, are recovered by the organ procurement organization for the service area in which the donor dies, as custodian of the organs, to be allocated by it either locally, regionally, or nationally in accordance with allocation policies established by the OPTN.

Section 11 includes two important improvements to previous versions of this [act]. First, it creates a priority for transplantation or therapy over research or education when an anatomical gift is made for all four purposes in a document of gift that fails to establish a priority.

Second, it specifies the person to whom a part passes when the document of gift merely expresses a "general intent" to be an "organ donor." This type of general designation is common on a driver's license. Under Section 11(f) a general statement of intent to be a donor results only in an anatomical gift of the donor's eyes, tissues, and organs (not the whole body) for transplantation or therapy. Since a general statement of intent to be an organ donor does not result in the making of an anatomical gift of the whole body, or any part, for research or education, more specific language is required to make such a gift.

Section 11(b) provides that, if an anatomical gift of the decedent's body or parts does not pass to a named person designated in a document of gift, it passes to a procurement organization typically for transplantation or therapy and possibly for research or education. Custody of a body or part that is the subject of an anatomical gift that cannot be used for any intended purpose

passes to the “person under obligation to dispose of the body or parts.” *See* Section 11(i).

Section 11(j) prohibits a person from accepting an anatomical gift if the person knows that the gift was not validly made. For this purpose, if a person knows that an anatomical gift was made on a document of gift, the person is deemed to know of a refusal to make a gift if the refusal is on the same document of gift.

Lastly, Section 11(k) clarifies that nothing in this [act] affects the allocation of organs for transplantation or therapy except to the extent there has been a gift to a named recipient. *See* Section 11(a)(2). The allocation of organs is administered exclusively under policies of the Organ Procurement and Transplantation Network.

In part, Section 14 has been redrafted to accord with controlling federal law when applicable. The federal rules require hospitals to notify an organ procurement organization or third party designated by the organ procurement organization of an individual whose death is imminent or who has died in the hospital to increase donation opportunity, and thus, transplantation. *See* 42 CFR § 482.45 (Medicare and Medicaid Programs: Conditions of Participation: Identification of Potential Organ, Tissue, and Eye Donors and Transplant Hospitals’ Provision of Transplant-Related Data). The right of the procurement organization to inspect a patient’s medical records in Section 14(e) does not violate HIPAA. *See* 45 CFR § 164.512(h) (“A covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye, or tissue donation and transplantation”). Section 14(c) permits measures necessary to ensure the medical suitability of parts to be administered to a patient who is being evaluated to determine whether the patient has organs that are medically suitable for transplantation.

Section 17 and Section 18 deal with liability and immunity, respectively. (Section 16, dealing with the sale of parts, also provides for potential liabilities but is essentially the same as prior law). Section 17 includes a new provision establishing criminal sanctions for falsifying the making, amending, or revoking of an anatomical gift. Section 18, in substance, is the same as the 1987 Act providing immunity for “good faith” efforts to comply with this [act]. However, while the [act] contains no provisions relating to bad faith it is important to note that other laws of the state and federal governments may provide for further remedies and sanctions for bad faith, including those under regulatory rules, licensing requirements, Unfair and Deceptive Practices acts, and the common law.

Section 18(c) provides that in determining whether an individual has a right to make an anatomical gift under Section 9, a person, such as an organ procurement organization, may rely on the individual’s representation regarding the individual’s relationship to the donor or prospective donor.

Section 19 sets forth rules relating to the validity of documents of gift executed outside of the state while providing that any document of gift shall be interpreted in accordance with the laws of the state.

Section 20 authorizes an appropriate state agency to establish or contract for the establishment of a donor registry. It also provides that a registry can be established without a state contract. While this [act] does not specify in great detail what could or should be on a donor registry, it does mandate minimum requirements for all registries. First, the registry must provide a database that allows a donor or other person authorized to make an anatomical gift to include in the registry a statement or symbol that the donor has made a gift. Second, at or near the death of a donor or prospective donor, the registry must be accessible to all procurement organizations to obtain information relevant to determine whether the donor or prospective donor has made, amended, or revoked an anatomical gift. Lastly, the registry must be accessible on a twenty four hour, seven day a week basis.

Section 21 creates a default rule to adjust the tension that might exist between preserving organs to assure their medical suitability for transplantation or therapy and the expression of intent by a prospective donor in either a declaration or advance health-care directive not to have life prolonged by use of life support systems. The default rule under this [act] is that measures necessary to ensure the medical suitability of an organ for transplantation or therapy may not be withheld or withdrawn from the prospective donor. A prospective donor could expressly provide otherwise in the declaration or advance health-care directive.

Sections 22 and 23 represent a complete revision of the relationship of the [coroner] [medical examiner] to the anatomical gift process. Previous versions of this [act] permitted the [coroner] [medical examiner], under limited circumstances, to make anatomical gifts of the eyes of a decedent in the [coroner's] [medical examiner's] possession. In light of a series of Section 1983 lawsuits in which the [coroner's] [medical examiner's] actions were held to violate the property rights of surviving family members, *see, e.g., Brotherton v. Cleveland*, 923 F.2d 477 (6th Cir. 1991), the authority of the [coroner] [medical examiner] to make anatomical gifts was deleted from this [act]. Parts, with the rare exception discussed in the comments to Section 9, can be recovered for the purpose of transplantation, therapy, research, or education from a decedent whose body is under the jurisdiction of the [coroner] [medical examiner] only if there was an anatomical gift of those parts under Section 5 or Section 10 of this [act].

This [act] includes a series of new provisions in Sections 22 and 23 relating to the relationship between the [coroner] [medical examiner] and procurement organizations. These provisions should encourage meaningful cooperation between these groups in hopes of increasing the number of anatomical gifts. Importantly, the section does not permit a [coroner] [medical examiner] to make an anatomical gift.